

Application No.: 10/664,764
Filing Date: September 17, 2003
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EXHIBIT I

Declaration of Dr. Andreas Burgard Under 37 C.F.R. §1.132

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, ANDREAS BURGARD declare and state that:

1. I am a resident of the Federal Republic of Germany.
2. I am a citizen of the Federal Republic of Germany.
3. I am a chemist having received a university degree in chemistry (equivalent to MS in chemistry) from Johannes Gutenberg University in Mainz, Germany.
4. From 1998 through September 2002 I was employed with Nutrinova Nutrition Specialties & Food Ingredients, GmbH ("Nutrinova"). My research for Nutrinova has generally focused on artificial sweeteners. For about 4 years my work focused on products incorporating the potassium salt of acesulfame, commonly referred to as acesulfame - K ("AcK").
5. I consider myself qualified by my knowledge of chemistry and by my years of experience in these technical fields for more than 12 years.
6. I am a co-inventor of the above-captioned United States Patent Application, i.e. application Serial No. 10/664,764, and therefore have personal knowledge of its subject matter.
7. I have read and understand the final Office Action mailed on February 18, 2005 ("the Office Action").

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8. I understand that Claims 1, 2, 6 and 10 stand rejected within the above-referenced application as being unpatentable over the combination of European Patent Application 0122400 to Nakajima ("Nakajima"), United States Patent No. 5,298,648 to Ebisawa et al. ("Ebisawa") and United Kingdom Patent Application 1297741 to Ninomiya et al. ("Ninomiya") in view of WIPO Publication No. 99/04822 to Ledniczky et al. ("Ledniczky") and WIPO Publication No. 00/12067 to Rayburn ("Rayburn").
9. Each of the primary references, i.e. Nakajima, Ebisawa and Ninomiya, are merely directed to conventional mixtures of individual chemicals.
10. The cited primary references thus merely evidence conventional wisdom at the time this invention was made that indicated the formation of a solution upon the dissolution of an artificial sweetener and a secondary component within a solvent.
11. In contrast, the claimed invention is directed to reacted chemical compounds, i.e. salts, and not just mixtures of various components in solution. The salts of the invention have significantly different properties than provided by mere mixtures, providing proof of the formation of a distinct chemical adduct rather than a mere blend. The differing physical properties exhibited by the inventive salts in comparison to conventional artificial sweetener blends are evidenced by the solubility and taste profile tests given below.

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12. Solubility Testing:

(a) Inventive Salt Preparation

A saccharin salt was formed by dissolving 0.05 mol of the acid form of saccharin (saccharin H) with 0.05 mol of arginine in 70 ml of water (at pH 7.4) at room temperature (23°C) with stirring for 30 minutes, which resulted in a clear solution. Afterwards the solution was dried under vacuum in a rotary evaporator. The dried residue was then further dried in a vacuum oven for 20 hr at 50°C until constant weight.

An acesulfame salt was formed by dissolving 0.05 mol of the acid form of acesulfame (acesulfame H) with 0.05 mol of histidine in 70 ml of water (at pH 7.4) at room temperature (23°C) with stirring for 30 minutes, which likewise resulted in a clear solution. Afterwards the solution was dried under vacuum in a rotary evaporator. The dried residue was then further dried in a vacuum oven for 20 hr at 50°C until constant weight.

The materials and absolute amounts used in the inventive salt formation described above are provided in Table 1 below:

TABLE 1:

<i>Material used:</i>	<i>amount used</i>
Saccharine Acid (Fluka, Art. Nr. 12475)	9.16 g
Acesulfamic acid (Nutrinova)	8.16 g
L-Histidine (Merck, Art. Nr. 1.04351)	7.76 g
L-Arginine (Fluka, Art. Nr. 11010)	8.71 g

(b) Comparative Mixture Formation

Comparative mixtures (i) and (ii) were formed by blending (i) 0.05 mol of sodium saccharin (commercially available from FluKa) with 0.05 mol of arginine and (ii) 0.05 acesulfame potassium (commercially

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available as SUNNETT® sweetener from Nutrinova) with 0.05 mol of histidine.

(c) Solubility Testing

A 5 g sample of each of the amino acid-sweetener salts noted in 12 (a) above were dissolved in increasing volumes of water (at pH 7.3) until a clear solution was achieved. The same molar amount of each of the blends (i) and (ii) of amino acid and commercially available sweetener noted in 12(b) above was likewise treated until complete dissolution was achieved. The amount of water added (in grams) was measured. The solubility in 100 grams of water was calculated from each of these measurements. The results are given in Table 2 below:

TABLE 2:

Amount	mols	Substance	Water needed for complete dissolution	Solubility in 100 g water
5.0 g	0.014	saccharine-arginine-salt	2.34 g	213.67 g
(5.82 g) 3.38 g 2.44 g	0.014 0.014 0.014	blend of Na-Saccharine L-Arginine	10.61g	54.85 g
5.0 g	0.0157	Acesulfam-Histidine-salt	3.68 g	135.87 g
(5.6 g) 3.16 g 2.44 g	0.0157 0.0157 0.0157	blend of Acesulfame-K L-Histidine	67.7 g	8.27 g

(d) Analysis

As shown in Table 2, the solubility of the saccharine-arginine salt in water is nearly 4 times higher than the solubility of the blend of sodium

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saccharin and arginine. Similarly, the solubility of the acesulfame-histidine salt is over 16 times higher than the blend of acesulfame K and histidine. Consequently, the data clearly indicates a significant improvement in the water solubility of amino acid-sweetener salts versus the corresponding blend of commercially available sweetener and amino acid.

13. Comparison of Taste Profile of Saccharin-Arginine Salt versus Sodium Saccharin/Arginine Blends

(a) Beverage Formation

A small quantity of saccharin-arginine salt was prepared as described in Paragraph 12 (a) above. A small quantity of a blend of sodium saccharin and arginine was prepared as described in Paragraph 12 (b) above.

A reference beverage was formed by dissolving the sodium saccharin/arginine blend in water, in the amount noted in Table 3 below. An inventive beverage was then formed by dissolving the saccharin-arginine salt in water, in the amount noted in Table 3 below. The concentration of the solution was chosen to give a sweetness intensity of approximately equal to that of an 8% sucrose solution.

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TABLE 3:

<i>substances</i>	<i>Amount (mg/l)</i>	<i>Molarity (mmol/liter)</i>
<u>Reference:</u>		
Na-Saccharine	200.0	0.8292
L-Arginine	144.4	0.8292
<u>Salt:</u>		
Saccharin-Arginine-Adduct	296.35	0.8292

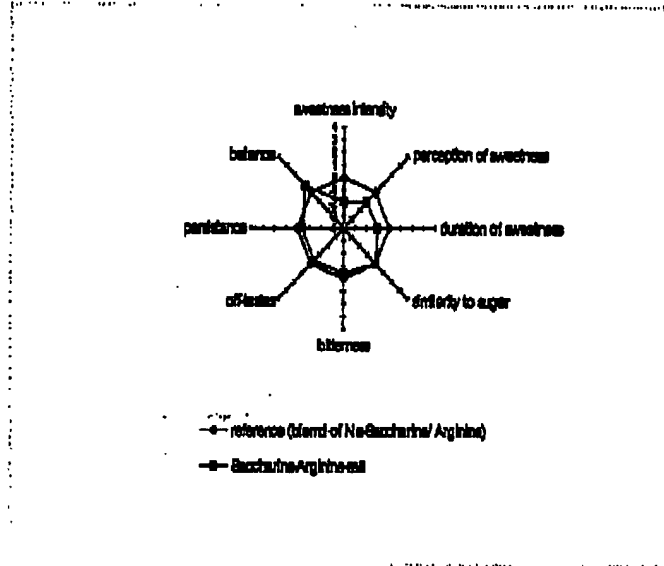
(b) Taste Testing

The two beverages were each tasted by a panel of seven trained tasters. The tasters were asked to rate the intensity of the six attributes given in Graph 1 for the saccharin-arginine salt beverage relative to the sodium saccharine/arginine blend beverage. For comparative purposes, the sodium saccharine/arginine blend beverage was used as the reference beverage (as noted above), consequently the intensities of each of the taste attributes of the sodium saccharine/arginine blend beverage were labeled as "0." The intensity of the taste attributes of the saccharin-arginine salt beverage was then ranked on a scale from + 4 to - 4 in comparison to the sodium saccharine/arginine blend beverage. The "plus" range indicated a stronger taste intensity in comparison to the reference beverage, while the "minus" range indicated a lower taste intensity in comparison to the reference beverage.

The result of this trial is depicted in Graph 1.

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GRAPH 1:



c) Analysis

Graph 1 clearly indicates a significant difference in the taste profile of the inventive salt in comparison to the reference blend. In particular, the salt has more overall balance, being slightly less sweet, having a delayed onset (perception) of sweetness and a lower peak intensity of the sweetness. Accordingly, the sensory trials further support the significant difference between the claimed artificial sweetener-amino acid salts and mere blends of commercially available artificial sweeteners and amino acids.

14. Based on the markedly differing physical properties, e.g. the elevated solubility and more balanced taste profile of the inventive salts in comparison to the corresponding blends, I respectfully reiterate that the claimed salts are distinctly different from the cited blends.

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14. Consequently, based on the data provided above in conjunction with my Declaration of November 3, 2004, I respectfully reiterate that the claimed invention is patentable in light of the art of record, considered either alone or in combination.
15. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statement may jeopardize the validity of the application or any patent issued thereon.

28.07.05

Date


Dr. Andreas Burgard